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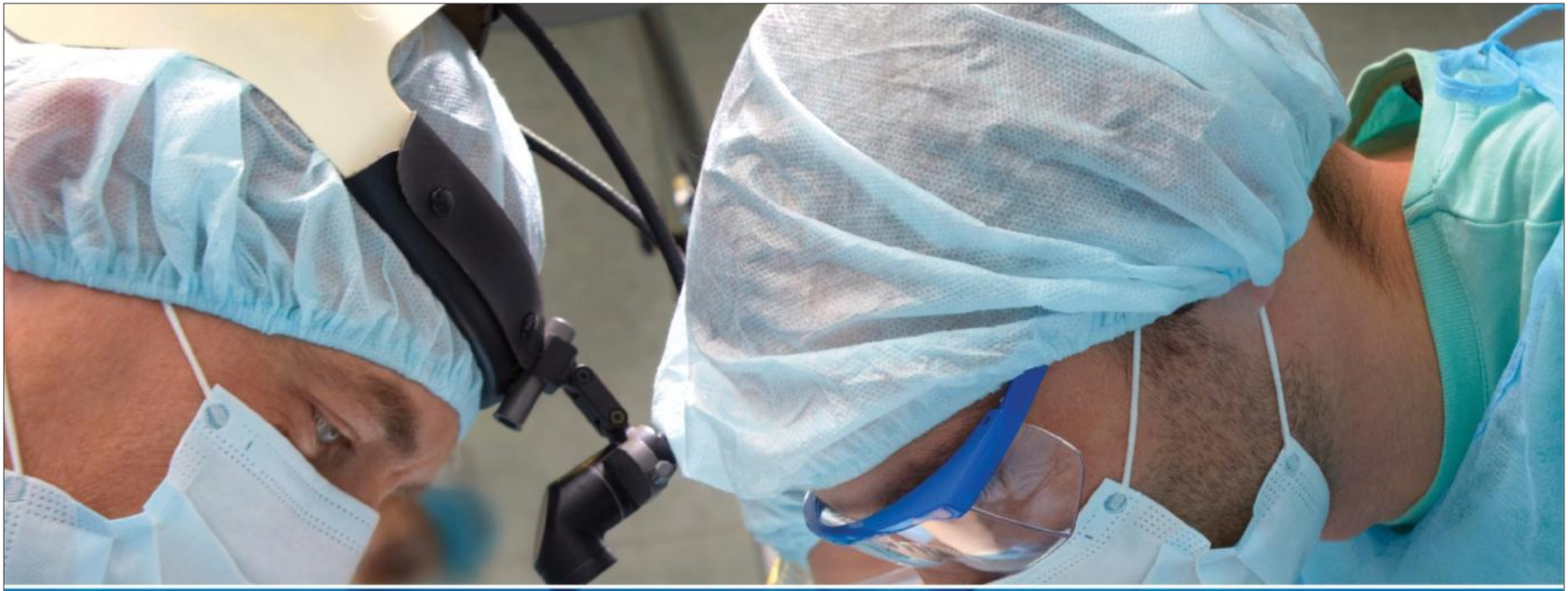
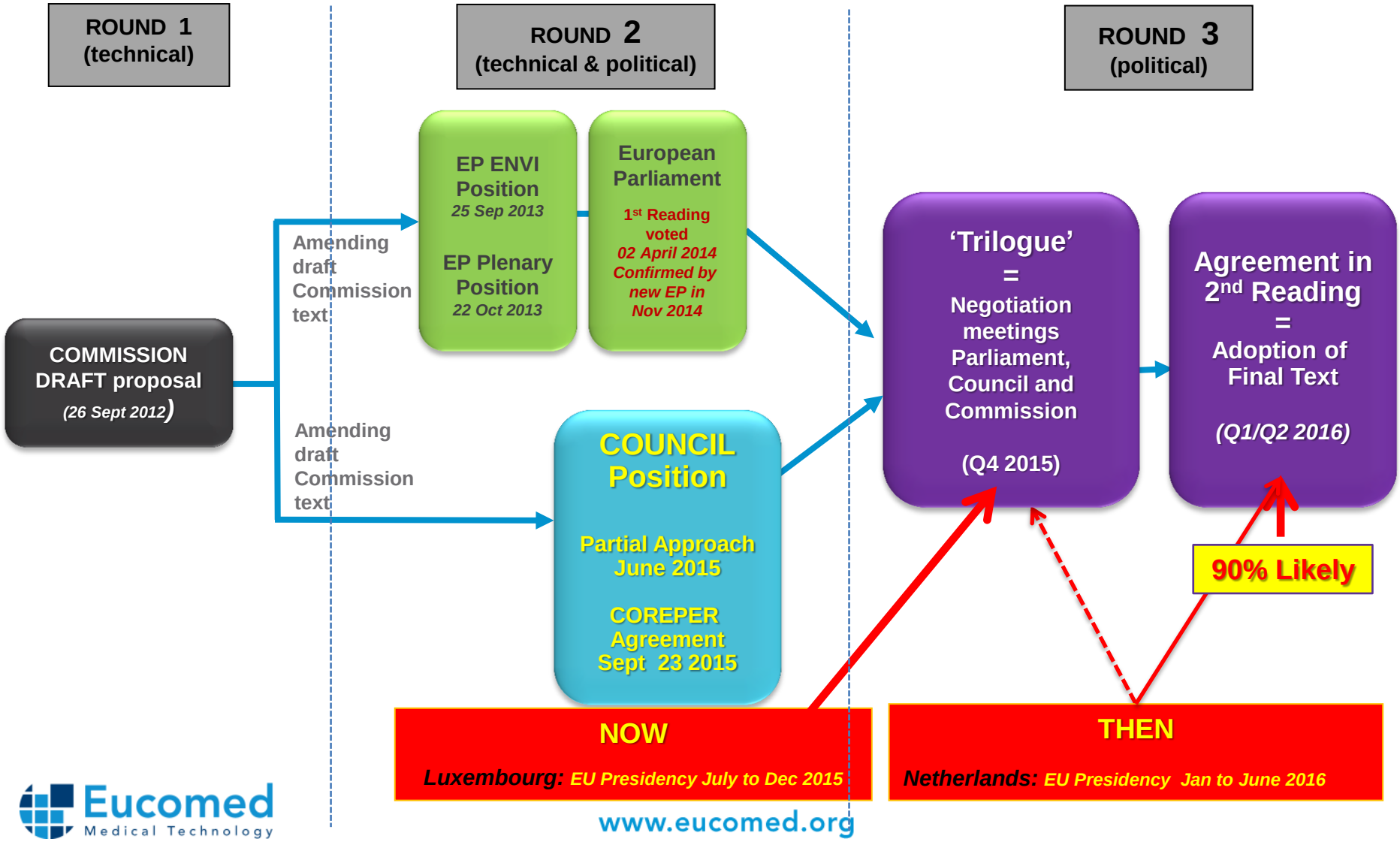


Medical Device Regulation: Update on key topics

Conferenza nazionale Dispositivi Medici, Roma 17-12-2015
Dario Pirovano – Senior Regulatory Adviser - Eucomed


edma
DIAGNOSTICS FOR HEALTH
Eucomed
Medical Technology
We are nearly there!
New medical device regulation
New in vitro diagnostic regulation
Before crossing the finish line,
let's have a final fitness check
Will each new measure:
1) See a real increase in patient safety?
2) Help rather than hinder needed innovation for patients?
3) Avoid unnecessary complexity for SMEs and Regulators?
More information: www.medtecheurope.org

Timeline : File is now progressing



Scrutiny

European Parliament

Implantable Class III + IIb admin/remove medicine + Human tissue

Stop-the-clock

Expert Committee (up to 600)

Committee decision

Council

Implantable Class III

No stop-the-clock

Expert Committee

Notified Body decision

Commission

New Class III

Stop-the-clock

Committee decision

Latest

Council scope + EP trigger

Or…

EP scope + Council process

EMA less likely

Clinicals

European Parliament

Increased transparency

Expanded limitation on clinical equivalence to include Class IIb administer or remove medicines

Council

Near re-write

Re-definition of clinical data

Limitation on clinical equivalence: class III and implantable from same manufacturer or 'data-access' contract in place

Commission

Align on Medicines as appropriate incl. transparency

Limitation on clinical equivalence: class III and implantable

Latest

Reaction to Council's [new] text:

"Highly technical"… "hard to understand reason for additional text"

EP beginning to question more strongly as understanding grows

Reuse of Single-Use devices

European Parliament

- Member State allowed ban
- All products reprocessable
- Reprocessor not the same as manufacturer
- Hospitals exempt

Council

- Ban; Member State's can allow
- Reprocessor the same as manufacturer
- Hospitals exempt

Commission

- Member State allowed ban
- Reprocessor same as manufacturer
- Hospitals exempt

Latest

- Gravitation to Council text
- Possible EP compromise

Hazardous Substances

European Parliament

De facto ban on CMR and Endocrine disruptors at >1%

Possible 4 year derogation (renewable based on certain criteria)

Council

Where risk of exposure, control of risk must be demonstrated

Information to user: labelling all listed hazardous substances (CMR 1A or 1B and endocrine disruptors) at >1%

Commission

Where risk of exposure, control of risk must be demonstrated

Information to user: labelling phthalates CMR 1A or 1B at >1%

Latest

Best case: Labelling of some sort

Worst case: Ban plus labelling

Presidency working on compromise

Greens working on compromise

Liability insurance

European Parliament

Manufacturers must also have appropriate liability insurance

Council

Manufacturers shall consider appropriate insurance or equivalent financial guarantee

Manufacturer not registered in EU => Authorised representative is liable for defective devices

Commission

Notified body to carry appropriate insurance

Insurance of subjects in clinical investigation

Latest

Support for appropriate insurance or equivalent financial guarantee for manufacturers

Debate seems to be about feasibility/appropriateness for authorised representatives

UDI

European Parliament

UDI to be coherent if possible with the global regulatory approach

More emphasis on UDI to prevent counterfeiting

UDI to be updated by voluminous data e.g. include results of the post market clinical follow-up evaluation report

UDI still on the DoC

Council

Introduction of new terms leading to inconsistencies with IMDRF

UDI to facilitate traceability but HC institutions no longer obliged to keep/store UDI records

UDI still on the DoC

Electronic system on UDI

Commission

UDI for traceability – economic operators and HC institutions to keep and store UDI records

Gradual risk class implementation

UDI on the DoC

UDI based on the IMDRF principles – to a possible extent

UDI seen as an integral part of Eudamed

Latest

In principle agreement to avoid differences with the IMDRF approach and system already in place (FDA)

Gradual risk class implementation

UDI will be an integral part of the Eudamed and not a separate database

UDI on DoC?

Eudamed

European Parliament

Even more transparency, more information to be included in Eudamed with more public access

Expansion of Eudamed to cover registration of subsidiaries and subcontracting as well as electronic system for special notified bodies

The information included in Eudamed to be robust, transparent and user friendly

Council

Near re-write of Chapter III and Annex V

Single registration number for Mfr and AR

Importers to be registered at the European level

National databases for importers and distributors to be allowed (fragmentation and loss of traceability?)

Eudamed to be subject to an independent audit assessing the functionality of he European Database

Commission

Central (Single) European database (Eudamed) covering registration, UDI, NB certificates, clinical investigations, vigilance and market surveillance

Registration of Mfr, AR and importers to reduce administrative burden by eliminating divergent national measures

Transparency

Latest

Work on development of the technical aspects of Eudamed begins….

Commission set up seven ad-hoc working groups to work on development of Eudamed – industry represented

Implant Card

European Parliament

- Card delivered with the device and electronically
- Card must e handled to patient by HCP
  - Identification of device + UDI
  - URL manufacturer
  - Warnings/Precautions
  - Expected lifetime
  - Adverse effects
  - Characteristics of device including materials
  - MS may require additional information on follow up
- Lay person language
- Some implants excluded, Implementing act to indicate other implants excluded

Council

- Information delivered with the device
  - Identification of device + UDI
  - URL manufacturer
  - Warnings/Precautions
  - Expected lifetime
  - Any other information
- Lay person language
- MS may require the information to be delivered to the patient
- Implementing act to indicate which implants are excluded

Commission

- Card delivered with device
  - Identification of device + UDI
  - Warnings/Precautions
  - Expected lifetime
- Lay person language
- All implants, no exclusions

Latest

EP likes the idea of a ‘card’

Classification

European Parliament

Reversal of some reclassifications:

- Substance based devices (Rule 21)

Council

Additional/modified reclassifications:

- Reusable surgical devices (Rule 6)
- Substance based devices (Rule 21)

Commission

Reclassification of a number of categories of devices e.g.:

- Spinal implants (Rule 8)
- Nanotechnologies (Rule 19)
- Substance based devices (Rule 21)

Latest

Major debate on Rule 6

Probable compromise on Rule 21